Randomized clinical trial

Randomized clinical trial of 270° posterior *versus* 180° anterior partial laparoscopic fundoplication for gastro-oesophageal reflux disease

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Background: **Partial fundoplications provide similar reflux control with fewer post-fundoplication symptoms compared with Nissen fundoplication for gastro-oesophageal reflux disease (GORD). The best choice of procedure for partial fundoplication remains unclear. The aim of this study was to compare the outcome of two different types of partial fundoplication for GORD.**

Methods: **A double-blind RCT was conducted between 2012 and 2015 in two hospitals specializing in antireflux surgery. Patients were randomized to undergo either a laparoscopic 270° posterior fundoplication (Toupet) or a laparoscopic 180° anterior fundoplication. The primary outcome was postoperative dysphagia at 12 months, measured by the Dakkak score. Subjective outcome was analysed at 1, 3, 6 and 12 months after surgery. Objective reflux control was assessed before and 6 months after surgery.**

Results: **Ninety-four patients were randomized to laparoscopic Toupet or laparoscopic 180° anterior fundoplication (47 in each group). At 12 months, 85 patients (90 per cent) were available for follow-up. Objective scores were available for 76 (81 per cent). Postoperative Dakkak dysphagia score at 12 months was similar in the two groups (mean 5·9 for Toupet *versus* 6·4 for anterior fundoplication; $P = 0{\cdot}773$). Subjective outcome at 12 months demonstrated no significant differences in control of reflux or post-fundoplication symptoms. Overall satisfaction and willingness to undergo surgery did not differ between the groups. Postoperative endoscopy and 24-h pH monitoring showed no significant differences in mean oesophageal acid exposure time or recurrent pathological oesophageal acid exposure.**

Conclusion: **Both types of partial fundoplication provided similar control of GORD at 12 months, with no difference in post-fundoplication symptoms. Registration number: NTR5702 (www.trialregister.nl).**

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Introduction

For patients suffering from gastro-oesophageal reflux disease (GORD) who are not responding to medical treatment or not willing to take life-long medication, laparoscopic fundoplication is currently considered the treatment of choice[1,2]. Previous studies have demonstrated comparable and durable subjective and objective reflux control, with a lower risk of surgical reintervention following laparoscopic fundoplication compared with open fundoplication[1,3]. Laparoscopic Nissen fundoplication has been the most frequently performed antireflux procedure[1,4,5]. However, the 360° posterior wrap in this fundoplication is associated with a high incidence of troublesome dysphagia and gas-related symptoms, such as gas bloating, flatulence and inability to belch[6–8]. Partial fundoplications have been developed as alternatives for the Nissen fundoplication, with the aim of reducing the incidence of such post-fundoplication symptoms[6,9–15]. The most commonly used partial fundoplications are either the posterior 270° fundoplication (Toupet) or the anterior 180° fundoplication[10,16].

Several RCTs[9,14,17–23] and meta-analyses[6,10,24] have evaluated whether partial wraps reduce post-fundoplication symptoms and whether this is at the expense of inferior reflux control compared with laparoscopic Nissen fundoplication[16]. Both laparoscopic Toupet[6] and laparoscopic 180° anterior[10] fundoplication provide similar reflux control, with a lower rate of postoperative dysphagia and gas-related symptoms compared with laparoscopic Nissen

fundoplication[6]. However, it is unclear which of these two partial fundoplications yields the best reflux control with minimal postoperative side-effects. Only two trials[25,26] have previously compared laparoscopic anterior with posterior partial fundoplication. The first[26] compared 120° anterior fundoplication with laparoscopic Toupet fundoplication and reported poor results after the anterior approach. However, the technique applied in the anterior arm might be inferior to a wrap with a 180° circumference. The second trial[25] used identical surgical techniques to those in the present study, but was underpowered.

The aim of the present study was to determine whether laparoscopic Toupet or laparoscopic 180° anterior fundoplication offers the best subjective and objective reflux control, with the fewest post-fundoplication symptoms.

Methods

This two-centre double-blind RCT compared two antireflux procedures: laparoscopic 270° posterior fundoplication (Toupet)[27] and laparoscopic 180° anterior fundoplication[28]. Differences in short-term reflux control, postoperative dysphagia and gas-related symptoms, and patient satisfaction were examined using upper gastrointestinal endoscopy, oesophageal manometry and 24-h pH monitoring, and questionnaires. The trial was designed in a similar fashion to that conducted in Australia[25]. Trial design was based partially on that protocol, with similar surgical methods, and similar questionnaires and follow-up intervals.

Ethical approval and trial registration

The protocol for this study was approved by the medical ethics committees of St Antonius Hospital, Nieuwegein, and the Isala Clinics, Zwolle (RCT no. NL39193.100.12). To guarantee safety and quality throughout the study, an independent data safety monitoring board was established, which has monitored the quality of the trial and followed the occurrence of all patient safety-related endpoints. A safety analysis was performed by the data safety monitoring board, and reported to the medical ethics committees when 50 per cent (47) of the patients had been included.

This trial was registered in the Netherlands Trial Register (NTR5702).

Study design

The study was performed as a randomized two-centre trial in two large teaching hospitals in the Netherlands, with all patients operated on by one experienced gastrointestinal surgeon (60 fundoplications annually; total caseload more than 400) per centre.

Patient selection

Adult patients with GORD confirmed by endoscopy and/or 24-h oesophageal pH monitoring, and with an indication for antireflux surgery, were considered eligible for inclusion. Patients who had undergone previous antireflux surgery and/or suffered from a large hiatus hernia (more than 50 per cent of the stomach in the chest), oesophageal aperistalsis, spasms or achalasia were excluded.

Randomization

After informed consent, 1 : 1 randomization to laparoscopic Toupet or laparoscopic 180° anterior fundoplication was performed using web-based randomization. Only patients who were deemed to be suitable for both procedures were randomized. Preoperative investigation was in accordance with standard clinical practice, which included upper gastrointestinal endoscopy, oesophageal manometry and 24-h pH monitoring. Oesophagitis was graded according to the Los Angeles classification[29]. The pH electrode was positioned 5 cm above the manometrically determined upper margin of the lower oesophageal sphincter (LOS). Preoperative barium swallows were performed only when clinically indicated, as barium swallows do not provide sufficient screening for GORD[30]. Patients were not informed of the type of fundoplication performed, and objective follow-up investigations were carried out by an observer blinded to the type of surgical procedure. Both hospitals had similar preoperative and postoperative care and investigation.

Surgical procedures

All fundoplications were performed using standardized laparoscopic techniques. Tutoring and a convention meeting between the two participating surgeons ensured similar techniques in both hospitals.

In all instances, the procedure commenced with dissection of the lower oesophagus and routine posterior hiatal repair using non-absorbable sutures. If present, the size and type of the hiatus hernia was assessed by the surgeon and noted in the case record forms. In none of the patients was a bougie used. Laparoscopic Toupet fundoplication entailed the creation of a posterior partial fundoplication of the gastric fundus, which was anchored to the oesophagus on left and right sides, as well as to the crus posterolaterally on the right side, while leaving the anterior oesophagus uncovered. When constructing a laparoscopic 180° anterior fundoplication, the ventral wall of the gastric fundus was sutured to the anterior oesophagus and right crus[31].

If the operation had to be converted to an open procedure, the patient remained included in the study. If the fundoplication type performed was not consistent with the allocated fundoplication, the patient was not excluded and remained in the allocated group for intention-to-treat analysis.

Postoperative care

Patients were allowed oral fluids directly, and soft solid food the next day. Early discharge from the hospital was usually on postoperative day 1 or 2. Barium meal X-ray was not performed routinely before discharge.

Primary outcome

The primary outcome was the difference in Dakkak dysphagia scores between the two study groups at 12 months after surgery, as assessed by validated questionnaires[32]. Reflux control was determined by means of upper gastrointestinal endoscopy and oesophageal 24-h pH monitoring 6 months after operation. All postoperative examinations were performed by gastroenterologists with extensive expertise in antireflux surgery and the associated changes in oesophagogastric anatomy.

The presence of reflux, dysphagia and gas-related symptoms was assessed at 1, 3, 6 and 12 months after surgery using standardized questionnaires. All patients were interviewed before the operation, and received these questionnaires by post. If a patient did not return these questionnaires within 1 month, they were reminded by telephone.

The presence or absence of the following symptoms was determined: heartburn, chest pain, epigastric pain, regurgitation, dysphagia, satiety, inability to belch, gas bloating, anorexia, nausea, vomiting, nocturnal coughing, flatulence and diarrhoea. In addition, the presence and degree of heartburn and dysphagia for liquids and solids was assessed using a 0–10 visual analogue scale (VAS) (0, no symptoms; 10, severe symptoms). The presence and degree of dysphagia was further examined using the validated Dakkak dysphagia score[32], which addresses the difficulty (0, never; 1, sometimes; 2, always) of swallowing nine types of liquid and solid.

The overall outcome of surgery was ranked using an analogue satisfaction score (0, dissatisfied; 10, satisfied), a modified Visick grading score[33] (1, no symptoms; 5, worse symptoms following surgery), the question whether the patient would undergo surgery again (0, no; 1, yes) and an overall outcome score (1, perfect; 4, bad outcome).

Changes in the use of proton pump inhibitors and histamine$_2$ blockers were also determined.

Sample size calculation

Sample size calculation was based on an estimated reduction in Dakkak dysphagia scores at 6 months of follow-up. A previous study[26] found a Dakkak dysphagia score of 7·0 following Toupet fundoplication. The aim was to reduce this score by a clinically relevant 50 per cent, to 3·5, following 180° anterior fundoplication at 12 months' follow-up, based on another clinical study[34] that reported a dysphagia score of 3·5 following anterior fundoplication. A two-sample *t* test power analysis, with a power of 0·8 and α of 0·05, was performed, resulting in a sample size of 47 in each arm (PASS 2008, version 8.0.8; https://www.ncss.com/software/pass).

Statistical analysis

All data were entered into a computerized database and analysed using the statistical software package SPSS® version 22.0 (IBM, Armonk, New York, USA). All included patients were analysed on an intention-to-treat basis, with a separate per-protocol analysis. No stratification analyses for centre were conducted. Data are expressed as mean (95 per cent c.i.) or total number of patients, unless indicated otherwise.

The χ^2 test, or Fisher's exact test where necessary, were used to compare binary variables between groups, and the Mann–Whitney *U* test for continuous variables. The Wilcoxon signed rank test was used for comparisons of the effects of surgery within either the laparoscopic Toupet or the laparoscopic 180° anterior fundoplication arm. Statistical significance was set at $P < 0{\cdot}050$.

Results

A total of 94 patients were included (*Fig. 1*). Forty-seven patients were randomized to laparoscopic Toupet and 47 to laparoscopic 180° fundoplication. Eighty-five (90 per cent) of these patients completed the questionnaires at 12 months after surgery. Objective follow-up data were available for 76 patients (81 per cent). During the 12-month follow-up, one patient withdrew from the study. Missing symptomatic or objective follow-up data were due to patients being lost to follow-up or their unwillingness to complete questionnaires or undergo postoperative investigations. Baseline characteristics of the patients are summarized in *Table 1*; there were no differences between the two groups.

Perioperative outcome

All 94 patients underwent the allocated surgical treatment and there were no conversions to open surgery.

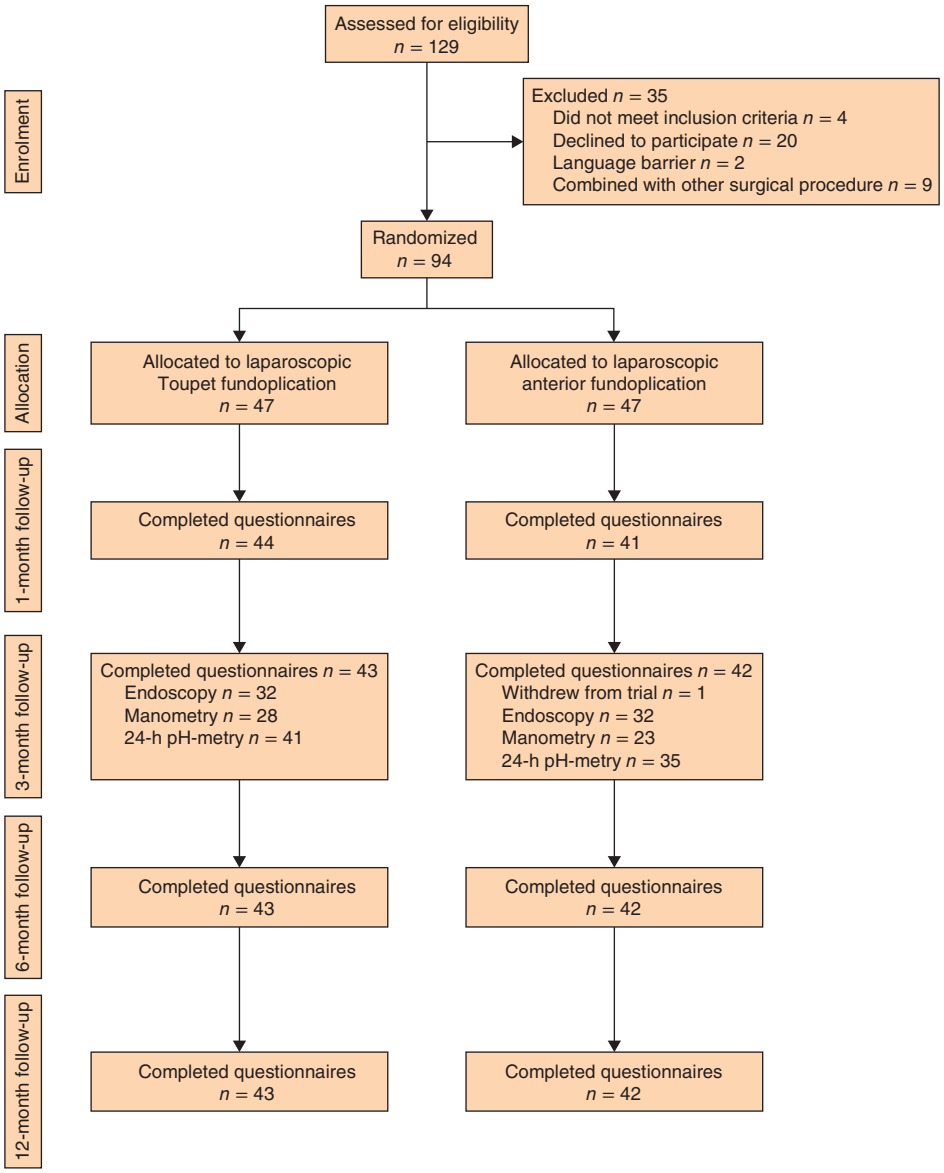

Fig. 1 CONSORT flow diagram of enrolment and follow-up of patients

Median operating time did not differ significantly between the two procedures (50 min for Toupet *versus* 43 min for anterior fundoplication; $P = 0{\cdot}091$) (*Table S1*, supporting information).

A hiatus hernia was present in 36 patients in the Toupet group and in 42 in the anterior fundoplication group ($P = 0{\cdot}251$) (*Table S1*, supporting information). Cruroplasty using non-absorbable sutures was carried out in all patients, with posterior cruroplasty being performed in 22 and 34 patients respectively, and posterior and anterior cruroplasty done more frequently after laparoscopic Toupet fundoplication (25 patients *versus* 13 in the anterior group; $P = 0{\cdot}012$) (*Table S1*, supporting information). None of the hiatus hernia repairs was done using mesh.

An intraoperative complication (a diaphragmatic bleed of 600 ml) occurred in one patient in the anterior fundoplication group. Postoperative complications within 30 days of surgery occurred in three patients in the Toupet group (acute dysphagia, 2; acute obstruction based on food stasis, 1) and in one patient in the anterior fundoplication group developed gastroenteritis. Revision fundoplication was performed in the two patients in the Toupet group who had acute dysphagia at 5 and 14 days after the primary operation. In both patients, the Toupet fundoplication was

Table 1 Baseline characteristics of patients undergoing laparoscopic fundoplication

	Toupet ($n = 47$)	Anterior ($n = 47$)
Age (years)*	54·0 (19–73)	56·0 (20–75)
Sex ratio (M : F)	24 : 23	23 : 24
BMI (kg/m^2)*	27·2 (19–41)	26·8 (19–37)
Duration of symptoms (years)*	5·0 (1–30)	5·0 (1–30)
Previous surgery†	17	22
ASA fitness grade		
I	21	14
II	24	27
III	2	3
Missing	0	3
Lost to follow-up at 1 year	4	5

*Values are median (range). †History of thoracic or abdominal surgery other than antireflux surgery.

Table 2 Assessment of preoperative and postoperative symptoms between the two types of laparoscopic fundoplication

	Before surgery		12 months after surgery		
	Toupet ($n = 47$)	Anterior ($n = 47$)	Toupet ($n = 43$)	Anterior ($n = 42$)	P*
Heartburn	44	41	9	6	0·422
Chest pain	31	35	7	7	0·962
Epigastric pain	23	28	7	7	0·962
Regurgitation	31	37	9	7	0·615
Pain during swallowing	3	6	3	0	0·081
Postprandial satiety	12	18	19	11	0·083
Inability to belch	0	0	6	4	0·526
Gas bloating	16	18	14	11	0·519
Anorexia	3	4	0	0	–
Nausea	18	14	6	4	0·526
Vomiting	8	15	2	0	0·157
Nocturnal coughing	17	12	7	3	0·191
Increased flatulence	–	–	26	21	0·160
Diarrhoea	0	0	5	6	0·715

*χ^2 or Fisher's exact test.

converted to a laparoscopic 180° anterior fundoplication, with no complications, and the dysphagia resolved.

Symptomatic outcome

Preoperative symptom scores for the two groups and symptomatic outcome at 12 months after surgery are summarized in *Tables 2* and *3*. Only increased flatulence (1 month: 27 *versus* 20 patients; $P = 0·034$) and chest pain (6 months: 10 *versus* 3 patients; $P = 0·039$) were observed significantly more often in the Toupet than in the 180° anterior fundoplication group.

In both groups there was a significant decrease in mean VAS score for heartburn at 12 months' follow-up compared with the preoperative score (Toupet: 1·3 *versus* 5·1 respectively, $P < 0·001$; anterior: 1·2 *versus* 4·6, $P < 0·001$) (*Table 3*). Mean heartburn score between the two groups was similar at 1, 3, 6 and 12 months after surgery. At 12 months, approximately 90 per cent of all included patients reported control of heartburn (39 of 43 patients in the Toupet group and 38 of 42 in the anterior group; $P = 0·944$).

At 12 months after surgery, seven patients in both the Toupet and anterior fundoplication groups reported the presence of dysphagia ($P = 0·962$). The 12-month VAS score for dysphagia for liquids did not change in either group compared with the preoperative score (Toupet: 0·5 *versus* 0·8 respectively, $P = 0·471$; anterior: 1·0 *versus* 1·0, $P = 0·411$); neither did the VAS dysphagia score for solids (Toupet: 1·1 *versus* 2·0, $P = 0·194$; anterior: 1·0 *versus* 1·9, $P = 0·107$) (*Table 3*). There were no differences between the two groups for any of the four follow-up intervals, with mean scores of 0·5 and 1·0 for liquids ($P = 0·313$) and 1·1 and 1·0 for solids ($P = 0·535$) in the Toupet and anterior fundoplication groups respectively at 12 months. Neither did the Dakkak dysphagia score differ significantly between the two groups at all four follow-up intervals, with mean scores of 5·9 and 6·4 respectively at 12 months (*Table 3*).

The patient satisfaction score (8·2 in both groups; $P = 0·679$), the Visick score (*Table 4*) and overall outcome ($P = 0·544$) were similar between the two groups at 12 months' follow-up, as well as at the other three intervals. At 12 months, 39 patients in the Toupet group and 40 in the 180° anterior fundoplication group reported that they would undergo the same operation again ($P = 0·676$).

Compared with preoperative usage, the use of acid-suppressing drugs decreased in both groups at the 12-month follow-up (from 44 of 47 patients to 9 of 43 in the Toupet group; from 43 of 47 to 9 of 42 in the anterior fundoplication group), with no significant difference in medication usage between the two groups at 12 months ($P = 0·950$). Per-protocol analysis based on the type of procedure patients had undergone at the time of completing follow-up, including the two cross-over patients in whom the Toupet procedure was converted to a laparoscopic 180° anterior fundoplication, did not influence the results, except that the higher rates of flatulence at 1 month ($P = 0·078$) and chest pain at 6 months ($P = 0·120$) in the Toupet compared with the anterior group were no longer significant.

Upper gastrointestinal endoscopy

Preoperative upper gastrointestinal endoscopy was performed in 90 patients (96 per cent) (*Table S2*, supporting information). Before surgery, reflux oesophagitis was present in 26 patients (29 per cent), with no differences

Table 3 Preoperative and postoperative control of heartburn and presence of dysphagia in patients undergoing laparoscopic fundoplication

	Before surgery		12 months after surgery		
	Toupet ($n = 47$)	Anterior ($n = 47$)	Toupet ($n = 43$)	Anterior ($n = 42$)	P†
Dakkak dysphagia score (0–45)*	8·6 (5·5, 11·6)	8·4 (5·3, 11·6)	5·9 (3·5, 8·3)	6·4 (3·8, 8·9)	0·773‡
Presence of dysphagia	16	18	7	7	0·962
VAS score*					
Liquids	0·8 (0·2, 1·3)	1·0 (0·4, 1·7)	0·5 (0·2, 0·8)	1·0 (0·4, 1·6)	0·313‡
Solids	2·0 (1·1, 2·9)	1·9 (1·2, 2·7)	1·1 (0·6, 1·6)	1·0 (0·3, 1·7)	0·535‡
Control of heartburn	16	11	39	38	0·944
VAS score for heartburn*	5·1 (4·1, 6·0)	4·6 (3·7, 5·1)	1·3 (0·8, 1·8)	1·2 (0·6, 1·7)	0·759‡

*Values are mean (95 per cent c.i.). VAS, visual analogue scale. †χ^2 or Fisher's exact test, except ‡Mann–Whitney U test.

Table 4 Symptoms assessed by Visick score

	Before surgery		12 months after surgery		
Visick score	Toupet ($n = 43$)	Anterior ($n = 42$)	Toupet ($n = 41$)	Anterior ($n = 38$)	P*
1	0	0	12	11	0·975
2	3	6	18	18	0·941
3	10	4	5	3	0·528
4	30	32	6	6	0·883
5	0	0	0	0	–

*χ^2 or Fisher's exact test.

between the two groups. Nineteen patients (21 per cent) suffered from Barrett's oesophagus. Endoscopy was used to verify reflux disease in the seven patients who did not have pH studies. In this group, no patient had grade A, three had grade B, one had grade C and none had grade D oesophagitis; a further three patients had Barrett's oesophagus.

Some 6 months after surgery, endoscopy was performed in 64 patients (68 per cent). Nine (14 per cent) showed signs of oesophagitis, and Barrett's oesophagus was found in 14 patients (22 per cent) (*Table S2*, supporting information), with no differences between the two groups ($P = 1·000$ for both comparisons). Per-protocol analysis did not change these results.

Oesophageal pH monitoring and manometry

A total of 76 patients (81 per cent) underwent 24-h oesophageal pH monitoring 6 months after surgery. Postoperative pH < 4 for more than 4 per cent of the time was found in four of 41 patients in the Toupet group and in four of 35 in the 180° anterior fundoplication group (*Table S2*, supporting information), with a mean percentage of time with pH < 4 of 1·9 in the Toupet group *versus* 2·6 in the anterior group ($P = 0·483$). Of these eight patients, one had normal oesophageal acid exposure before fundoplication. Only one patient reported typical reflux symptoms (regurgitation) at 3 and 6 months after surgery, and none of these eight patients reported heartburn. Per-protocol analysis did not affect these results.

Preoperative oesophageal manometry was performed in 55 (59 per cent) of the 94 included patients, and did not demonstrate abnormalities or significant differences between the two groups. Six months after surgery 51 patients (54 per cent) underwent oesophageal manometry again, which revealed a significantly lower mean residual resting pressure in the Toupet group than in the anterior group ($P = 0·008$) (*Table S2*, supporting information). Per-protocol analysis did not change these results.

Discussion

This RCT found no difference between the two types of partial fundoplication in controlling the symptoms and oesophageal acid exposure associated with GORD. Few postoperative side-effects were found in either arm, and patient satisfaction rates were high. Based on the 12-month results of this trial, the authors suggest that selecting a laparoscopic 270° posterior (Toupet) or 180° anterior fundoplication should be based on surgeons' experience and preference.

The Dakkak dysphagia score was the primary outcome of this trial, and no differences between the two groups were identified at 1, 3, 6 and 12 months of follow-up. There were no differences in secondary outcomes such as reflux control, overall outcome and patient satisfaction. The only differences that were observed included a higher rate of flatulence 1 month after Toupet fundoplication and of chest pain 6 months after laparoscopic Toupet fundoplication. At 12 months these differences were no longer present. The presence of typical post-fundoplication symptoms also did not differ significantly between the two groups.

An RCT[25] comparing laparoscopic Toupet with laparoscopic 180° anterior fundoplication found no significant differences in terms of dysphagia, but a trade-off between reflux *versus* inability to belch and nausea. Heartburn scores were higher after 180° anterior fundoplication,

accompanied by a trend towards higher pH scores. Satisfaction after both procedures was similarly high[25]. The present study randomized twice as many patients and the results are in line with the findings of Daud and colleagues[25], with no major differences in reflux control and post-fundoplication symptoms between laparoscopic Toupet and 180° anterior fundoplication.

A possible advantage of a laparoscopic 180° anterior over Toupet fundoplication could be the fact that the anterior fundoplication requires less division of short gastric vessels. However, the present authors did not find a significant difference in total duration of surgery, indicating equal technical feasibility of the two procedures.

The manometric studies are in line with those of Daud and co-workers[25], reporting a trend towards reduced LOS resting and residual pressures after Toupet compared with 180° anterior fundoplication. These manometric results are in contrast with those from a Swedish trial[35] in which a trend toward higher LOS resting and residual pressures after Toupet fundoplication was found compared with pressures following anterior fundoplication. A possible explanation for these conflicting results may be the fact that the latter trial used a 120° anterior fundoplication technique, which may be inferior to the 180° approach used by Daud *et al*.[25] and in the present trial. This might have resulted in different lower postoperative oesophageal sphincter resting and residual pressures[35]. Despite a significantly lower LOS residual resting pressure in the Toupet group compared with that in the 180° anterior group, no difference was found in oesophageal acid exposure during 24-h oesophageal pH monitoring in the present study, indicating that the decrease in LOS residual resting pressure did not result in an increase in acidic reflux episodes. Continuing follow-up, including oesophageal function testing, will determine whether this finding has any long-term clinical implications. LOS length was not registered adequately in manometric studies, so it is not possible to determine whether the reduced LOS pressure in the Toupet fundoplication arm was due to a shortening of the LOS length.

The effectiveness on patient's well-being of both procedures is demonstrated by high patient satisfaction and Visick scores. These findings are in line with those of other trials[25,36]. At least 93 per cent (79 of 85) of all included patients would undergo surgery again under similar conditions. Furthermore, approximately 90 per cent of all patients reported control of heartburn, and a significant reduction in mean heartburn scores was seen at 12 months, demonstrating the excellent reflux-controlling potential of both procedures.

A possible weakness of the present study is the fact that not all of the included patients underwent postoperative oesophageal 24-h pH monitoring, which is considered the standard for diagnosing GORD. It remains difficult to convince patients of the need for invasive postoperative oesophageal function testing if they experience no postoperative symptoms. This is a common problem in prospective studies describing the outcome of antireflux surgery. However, postoperative 24-h oesophageal pH studies were obtained for 81 per cent of the patients, with no significant differences between the two groups, and demonstrating pH < 4 for more than 4 per cent of the total time in four of 41 patients after Toupet and four of 35 after 180° anterior fundoplication, of whom only one patient reported regurgitation and none reported heartburn. A study by the authors' group[37] comparing the results of laparoscopic Nissen and 180° anterior fundoplication found no differences in outcome between patients who had only subjective outcome assessment and those who completed both subjective and objective follow-up. Furthermore, there were no significant differences in symptomatic outcome between laparoscopic Toupet and 180° anterior fundoplication groups, making it unlikely that a higher rate of patients undergoing postoperative pH monitoring would result in a significant difference in recurrent pathological acid exposure between the two groups.

Investigator bias is deemed unlikely as both surgeons conducted the operations in a similar fashion after training together in the two procedures and performing them on patients together, as well as discussing intraoperative videos of the two techniques before commencement of the trial. There was no learning curve, as both surgeons are experienced in reflux and upper gastrointestinal surgery[38]. In addition, a two-centre design and intention-to-treat analysis is probably the best reflection of clinical practice.

There were no differences in typical reflux symptoms such as heartburn and regurgitation, or in oesophageal acid exposure. Based on objective oesophageal studies 6 months after surgery, only LOS residual resting pressure was found to be lower for the Toupet procedure compared with 180° anterior fundoplication. These findings were not reported in other comparable trials[25,36].

Disclosure

The authors declare no conflict of interest.

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Supporting information

Additional supporting information may be found in the online version of this article:

Table S1 Perioperative outcome of patients undergoing laparoscopic fundoplication (Word document)

Table S2 Preoperative and postoperative outcome of objective studies of patients undergoing laparoscopic fundoplication (Word document)

Editor's comments

In antireflux surgery, collective data have suggested better outcomes with a partial fundoplication in terms of control of symptoms after fundoplication when compared with a full wrap. Which type of partial wrap method to choose has been less clear. In the current randomized trial, a posterior wrap (Toupet) was compared with an anterior one (Dor). The primary outcome was assessed for difference at 1 year using the Dakkak score. The Dakkak score (range 0–45) indicates either no dysphagia (45) or no symptoms (0). No difference in rate of dysphagia at 1 year was found for either method, with scores of around 6. The number of patients with dysphagia was more than halved after 1 year, yet persisted in a subgroup of approximately 17 per cent of patients in each group. As the results of fundoplication surgery are generally best in patients who have seen an effect with acid-suppressive drugs, but are unwilling to use life-long medication, the current results should help inform on both the efficacy of the two types of partial fundoplication and the risk of persistence of symptoms in some patients despite surgery. How this will fare with longer term follow-up will be of interest (see next paper).

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Editor, BJS